## REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the following comments.

The sole issue for consideration is the rejection of claims 7, 9-12 and 15 under 35 USC § 112, first paragraph, as being broader than the enabling disclosure. According to the Examiner, the instant specification does not enable any person skilled in the art "to make/use the invention commensurate in scope with these claims." Applicants respectfully disagree, and respectfully request that the Examiner reconsider and withdraw this rejection.

Allegations in the specification ***must*** be accepted as true in the absence of reasonable doubts supported by sound technical reasoning or evidence. *In re Marzocchi et al.*, 169 USPQ 367, 369 (CCPA 1971). The Examiner has not provided any sound technical reasoning or evidence tending to cast any doubt on the enablement. Therefore, the Examiner's position is untenable as a matter of law and must be reconsidered and withdrawn.

The Examiner says the enablement is not commensurate in scope *with these claims*. Quite to the contrary, these claims were "designed" so that enablement could *not* be an issue.

The instant claims, as exemplified by claim 7, are drawn to antimicrobial compositions comprising an amount of a combination of a first ingredient, which is cyproconazole, and a second ingredient, which is a fungicide or insecticide other than cyproconazole. Most

importantly, the amount of the combination is expressly required to be "a synergistically effective amount," which means that the claims expressly exclude any combinations that are not, in fact, synergistic. In other words, the claims *are limited by this functional language to operative compositions only,* and, therefore, the Examiner has no good reason to doubt the enablement.

Indeed, the Examiner says he accepts the enablement for the synergistic combinations shown in the declaration evidence of record (although, for some reason, not even species claims 11 and 12 are allowed.) Thus, the Examiner accepts that combinations of cyproconazole and other fungicides or insecticides will synergize.

Obviously, the Examiner is concerned about the relationship between the claims and the showing. However, as explained above, Applicants submit that the claims have been tailored with the use of the functional language to make them *exactly commensurate in scope with this showing*. Thus, the instant claims only cover combinations of cyproconazole and another fungicide or insecticide that are, in fact, synergistic. The instant claims do not cover combinations of cyproconazole and another fungicide or insecticide that are not synergistic.

The specification teaches the types of fungicides and insecticides that may be combined with cyproconazole to produce a synergistic effect beginning at page 9, line 15, continuing over to page 16, line 13. It is expressly taught at page 9, lines 20-23, that many of these combinations

will be synergistic. Amounts that may produce synergistic results are taught at page 16, lines 14-20.

Respectfully, there is no good reason to doubt the enablement for the present claims. In order to confirm the composition is synergistic, it is only necessary to make the composition, and then test whether the composition is synergistic. The first ingredient is a well-known ingredient, and many of the second ingredients are also well-known. Accordingly, there is no doubt that a person skilled in the art can make a combination of a first ingredient and a second ingredient, as instantly claimed. The only question then is whether such a person can test whether such combination is synergistic, and Applicants submit that there is no doubt here either, as tests for synergy are well-known in this art, and, therefore, a person skilled in the art should have no difficulty determining whether a given combination made is synergistic.

While it is true that it will require some amount of experimentation to make and test combinations in the manner suggested above, such making and testing does not involve undue experimentation, as all experiments are routine, and, moreover, persons skilled in this art are accustomed to making and testing large numbers of such compositions.

As the Court explained in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), "[e]nablement is *not* precluded by the necessity for some experimentation such as routine screening." Further, on the same page, they quoted with approval the following quote from *In re Jackson*, 217 USPQ at 807 (POBA 1982):

> "The test [for undue experimentation] is *not* merely quantitative, since a *considerable* amount of experimentation is permissible, if it is merely routine, *or* if the specification in question provides a reasonable amount of guidance with respect to the direction the experimentation should take. [Emphasis added.]"

Not only is any experimentation required here straight-forward, conventional and routine, but the specification also provides a reasonable amount of guidance with respect to the direction the experimentation should take in teaching that synergy is possible, in providing examples of suitable combination partners and in providing exemplary amounts of each ingredient to use. Accordingly, *both* prongs of the *Jackson* "test" are met and, therefore, although some experimentation would be required to practice the full scope of the instant invention, any required experimentation is *not* undue.

On the issue of predictability, Applicants would call the attention of the Examiner to the decision in *Ex parte Mark*, 12 USPQ2d 1904 (BPAI 1989), wherein the Board of Appeals found a specification was enabling despite the fact that there was *actual evidence of inoperability*, thereby, leading to a total lack of predictability. (As will be explained below, the present case is, thus, "better" since there is no actual evidence of inoperability.)

The invention in *Mark* required the identification in a native protein of free cysteine groups that were *nonessential* to the biological activity of the native protein. The claims related, among other things, to muteins in which at least one of the identified nonessential cysteines was

replaced by another amino acid. The essence of the invention was the discovery that the muteins retained the biological activity of the native protein.

However, as stated above, the invention was *completely unpredictable.* In other words, it was not clear beforehand which cysteines were "nonessential" and, therefore, could be replaced without a loss of the biological activity of the native protein.

Indeed, as stated above, there was *actual evidence* that certain cysteines could not be replaced without a loss of the biological activity of the native protein. Thus, there was prior art that showed that a mutein having a specific cysteine 6 tyrosine replacement did *not* retain the biological activity of the native protein. In addition, there was data in a related application of applicants therein, which showed that seven other cysteine 6 serine substitutions resulted in a substantial reduction in biological activity.

Against this backdrop, the examiner therein found that it would require undue experimentation to construct the "innumerable" muteins encompassed by the claims therein and then to screen the muteins produced to determine which retained biological activity.

The examiner therein pointed to the loss of activity with the substitutions mentioned above. The examiner therein also pointed out that most cysteines were essential to proper protein folding and, thus, activity and, consequently, most of the muteins prepared by applicants therein would be expected to be less active than the native protein. Further, the examiner therein

also took the position that the mere sequencing of all possible proteins encompassed by the claims would entail undue experimentation.

In spite of what the examiner therein undoubtedly viewed as a very good case for nonenablement, the Board decided in favor of applicants therein.

The reasons for that decision merit very close examination.

The Board noted that a declaration was provided that set forth a "reasonable", "step-by-step" scheme, which, if followed, would allow a person of ordinary skill in the art to determine in a simple, straight-forward manner whether a given cysteine was essential or nonessential. In other words, it was routine to determine whether a particular embodiment was operative.

Also, the claims therein were limited by functional language to only operative embodiments.

Given the foregoing, the Board found that the disclosure was enabling because *the claims were expressly limited by functional language to muteins that retained biological activity and there was a straight-forward scheme* by which it could be determined whether a given mutein retained biological activity. Although operability was highly unpredictable, the Board reasoned that one skilled in the art would be able to determine routinely whether a given cysteine was

nonessential and, therefore, when replaced or deleted would result in a mutein within the claims therein.

In the present case, the instant claims are also limited to operative embodiments only by functional language, and a straight-forward scheme for determining synergistic embodiments is also presented by way of declaration, which straight-forward scheme takes the making and testing form explained above.

Even if the Examiner had well-founded concerns whether every combination of cyproconazole and a second fungicide or insecticide would be synergistic, any non-synergistic embodiments are *not* within the present claims since the present claims expressly require that the combination contain "a synergistically effective amount" of the two ingredients. Thus, the instant claims provide the same "functional" language "safeguards" as were provided by the claims in *Mark*.

In view of the foregoing, Applicants respectfully submit that the Examiner would be fully justified to reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Request for Reconsideration Under 37 CFR § 1.111 and accompanying Petition for Extension of Time (10 pages total) are being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: March 18, 2003

By _____
Kurt G. Briscoe